

## **Section 6: Summary of Safety and Effectiveness**

---

(Pursuant To Section 12 of the SAFE MEDICAL DEVICES ACT of 1990)

### **6.1 General Provisions**

<b>Submitter's Name and Address</b>	Boston Scientific Corporation One Scimed Place Maple Grove, Minnesota 55311
<b>Contact Person</b>	Heidi M. Erickson (763) 494-2564
<b>Classification Name</b>	Diagnostic Intravascular Catheters (21CFR Part 970.1200)
<b>Common or Usual Name</b>	Angiographic Catheter
<b>Proprietary Name</b>	Boston Scientific Imager™ II 4F Selective Angiographic Catheter

<b>6.2.1 Name of Predicate Device</b>	Boston Scientific Imager™ II 4F, 5F Flush and 5F Selective Angiographic Catheter
---------------------------------------	---

---

### **6.3 Device Description**

The IMAGER™II Angiographic Catheters are designed to provide a pathway for delivering contrast media to selected sites in the vascular system. The IMAGER™II Angiographic Catheters are sterile, single-use diagnostic intravascular catheters and are available in a variety of flush and selective curve styles with lengths of 40 cm, 65 cm, 90cm and 100 cm. The distal segment of the catheter is radiopaque to aid in visualization of the device under fluoroscopy.

---

### **6.4 Intended Use**

The IMAGER™ II Angiographic Catheters are designed to provide a pathway for delivering contrast media to selected sites in the vascular system.

---

## **Section 6: Summary of Safety and Effectiveness**

---

### **6.5 Summary of Technological Characteristics**

Same as currently marketed Imager™ II Angiographic Catheters, cleared for market under K011664, September 7, 2001.

---

### **6.6 Non-clinical Test Summary**

Functional testing consisted of dimensional verification, guidewire compatibility, tensile strength, torque response, insertion force, static burst strength, and flow rate.

Biocompatibility and product shelf life testing were previously conducted on the predicate devices. Test results verified that the 4F Selective Imager™ Angiographic Catheters are adequate for the intended use. The 4F Selective Imager™ II Angiographic Catheters are considered substantially equivalent to the currently marketed 4F and 5F Flush and 5F Selective Imager™ Angiographic catheters based on a comparison of the intended use, the device design, and the results of testing and evaluation.

---



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 4 2002

Boston Scientific Corporation  
c/o Ms. Heidi M. Erickson  
One Scimed Place  
Maple Grove, MN 55311

Re: K022621  
Boston Scientific Imager™ II 4F Selective Angiographic Catheter  
Regulation Number: 870.1200  
Regulation Name: Diagnostic Intravascular Catheter  
Regulatory Class: Class II (two)  
Product Code: 74 DQO  
Dated: August 6, 2002  
Received: August 7, 2002

Dear Ms. Erickson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807);

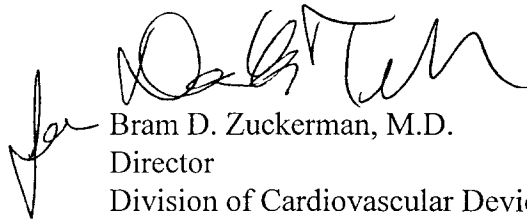
Page 2 - Ms. Heidi M. Erickson

labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over the printed name and title.

Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Section 4: Indications for Use

510(k) Number (if known) \_\_\_\_\_

Device Name: 4F Selective Imager™ II Angiographic Catheter

Indications for Use:

The IMAGER™ II Angiographic Catheters are designed to provide a pathway for delivering contrast media to selected sites in the vascular system.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)


\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over The Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K022621